Summary of Hib (PedvaxHIB®) recall 12/13/2007

- The PedvaxHIB® doses from recalled lots that have been given to children will require no action. There have been no reports of adverse events from administration of vaccine with these lot numbers. The doses administered do count and will not have to be repeated. There is no problem with vaccine potency.

- The precautionary, voluntary recall was implemented because Merck could not assure sterility of the vaccine from the lot numbers listed in the memo dated Dec. 13, 2007.

- The Postage Paid Business Reply Card and the Packing Slip may be obtained by calling Stericycle at one of the following phone numbers: (877) 860-1200 or (800) 668-4391.

- You must account for the VFC vaccine and privately purchased vaccine separately in the paperwork returned to Stericycle.

- Please complete the Montana Wasted and Expired Vaccine Return Form and fax it back to the Immunization Program at 406-444-2920. This will allow us to determine where the greatest immediate need is as we determine future Hib shipments.

- Merck produces approximately 50% of the nation's Hib vaccine supply, and it is not yet known when they will resume full production of the vaccine. Sanofi, the other Hib manufacturer, is checking on their ability to supply the U.S. need.

- A panel including the CDC, ACIP, AAP, AAFP and FDA will be meeting on December 14, 2007 to discuss Hib vaccine supply issues. Any information regarding a possible change in schedule will come out next week. Information regarding VFC Hib vaccine supply will be shared when we receive additional information.

- No Hib orders for VFC supply will be accepted until the CDC has given us the information regarding our monthly allocation, determined following tomorrow's meeting described above.

- American Indian and Alaska Native children, children who are asplenic and those considered to be immunodeficient are considered to be at highest risk. They should continue to receive a complete Hib schedule.